UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., Plaintiff, v. FRESENIUS KABI USA, LLC, Defendant.	Civil Action No. 14-4989 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Merck Sharp & Dohme Corp. ("Merck") and Defendant Fresenius Kabi USA, LLC ("Fresenius"). In this patent infringement suit involving a pharmaceutical patent, the parties seeks construction of claims in U.S. Patent No. 5,952,300 ("the '300 patent").

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed term

Claim 1 states:

> 1. A pharmaceutical composition for intravenous administration to a patient comprising
>
> a) a pharmaceutically effective amount of a compound having the formula [] and the pharmaceutically acceptable salts thereof,
>
> b) a pharmaceutically acceptable amount of an excipient effective to form a lyophilized cake; and
>
> c) a pharmaceutically acceptable amount of an acetate buffer effective to provide a pharmaceutically acceptable pH.

The parties dispute whether the claim language requires element (c) to be "separate and distinct," as Fresenius contends. Merck argues that the claim language requires an acetate buffer to be present in the composition. This Court agrees with Merck.

Frensenius proposes an interpretation that does not make sense, on a number of levels. A serious problem is immediately apparent: what does "separate and distinct" mean in the context of a pharmaceutical composition? Compositions generally involve the mixing together of things. As the Federal Circuit has stated, "[t]he term 'composition' in chemistry is well-established. It generally refers to mixtures of substances." PIN/NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1244 (Fed. Cir. 2002). If this Court were to adopt the construction proposed by Fresenius, it would then be faced with the difficult problem of figuring out how one can mix substances while keeping them separate and distinct. Proceeding in this direction is confusing, not clarifying.

Additional confusion comes from a lack of clarity about the time frame in which the acetate buffer should be separate and distinct. It is unclear whether Fresenius contends that the acetate buffer should be separate and distinct just prior to mixing, or after. Defendant's opening

brief speaks repeatedly about "adding an acetate buffer as a separate ingredient," and, "an acetate buffer has to be separately added," which invokes the time frame prior to mixing.[1] (Def.'s Opening Br. 1.) In its responsive brief, however, Fresenius argues that its proposed construction does not refer to the process by which the composition is made, and that it requires only that the acetate buffer be present in the composition, which invokes the time frame after mixing.

Defendant's position is thus inconsistent and unclear. One possible explanation is that, in its responsive briefing, Fresenius backtracked from the added separate ingredients approach and switched to a separate mixed elements-in-composition approach. As already stated, the separate mixed elements idea is mysterious and unexplained: Fresenius has never articulated what it means for an element in a pharmaceutical mixture to be separate and distinct. Fresenius has not explained what this means or how this is possible.

Moreover, although Fresenius purports to propose a claim construction, it does not base the "separate and distinct" limitation on any issue of the meaning of the words in the phrase, "a pharmaceutically acceptable amount of an acetate buffer effective to provide a pharmaceutically acceptable pH." The closest Fresenius comes to basing its proposed construction on claim language comes when it argues that the "comprising" structure of the claim implies a "separate and distinct" limitation. In support, Fresenius cites the Federal Circuit's decision in Becton, Dickinson & Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010): "Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention."

[1] This is puzzling. Why would claim language in a composition claim refer to any time frame other than the time in which the composition exists?

Fresenius has misinterpreted what the Federal Circuit held. In the context of a medical device patent, the Federal Circuit held that two separately-listed claim elements cannot be the same structure. Id. The Federal Circuit did not state that two separately-listed claim elements of a composition must be separate, whatever that means.

Fresenius appears to be treading on confusing conceptual distinctness with concrete physical characteristics. The elements of a claim need not be physical things, and they do not need to be physically distinct things, but they do need to be logically or conceptually distinct. Becton stands for the proposition that one separately-listed element cannot be identical to another. If two separately-listed elements are identical, the two lack conceptual distinctness; Becton did not involve issues of physical distinctness.

Moreover, as Merck contends, rather than clarifying the meaning of unclear claim language, Fresenius seeks to import additional limitations into the claim. At the outset, as Merck observes, it is fundamental patent law that "[w]e do not read limitations from the specification into claims." Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1366 (Fed. Cir. 2012). This alone is good reason to reject Defendant's arguments based on the specification.

Fresenius also contends that the applicant's statements to the USPTO during prosecution support its construction. The standard for restricting claim scope based on such statements is a demanding one: "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." August Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278, 1286 (Fed. Cir. 2011). None of the statements Fresenius cites manifest a clear disavowal of claim scope.

Fresenius first points to a statement by the applicant in response to an obviousness

rejection. The examiner had rejected a claim as obvious in view of a number of patents, including the Webb patent. In submitting an amendment, the applicant stated:

> The Webb patent discloses pharmaceutical compositions of peptides which are structurally different from the compound of the invention. While the particular buffer is disclosed, it is the unique combination with the particular compound that is the subject of the invention.

(Tarantino Dec. Ex. 3 at 7-8.) The Court does not perceive a clear disavowal of any claim scope in these statements. To the contrary, the applicant appears to argue the same point that Merck argues here: it is the unique combination of the buffer with the particular active compound that is the subject of the invention.

Next, Fresenius cites a response to an office action, dated August 5, 1998. Fresenius notes that "Merck pointed specifically to examples in the patent where caspofungin acetate was the active ingredient, and where an acetate buffer was separately added – instead of caspofungin acetate by itself or in combination with other buffers." (Def.'s Opening Br. 6-7.) This does not manifest a clear disavowal of claim scope.

Fresenius cites two more portions of the prosecution history with similar statements. None manifest a clear disavowal of claim scope.

Fresenius argues that Merck's proposed construction effectively deletes component (c) from claim 1. That is incorrect. Merck has not proposed a construction which eliminates the requirement that the invention, according to claim 1, contain an acetate buffer. To the contrary, Merck's proposed construction clearly requires the presence of component (c).

In support of its construction, Merck points to the decision by a Delaware district court in Merck Sharp & Dohme Corp. v. Xellia Pharm. ApS, No. CV 14-199-RGA, 2015 WL 82386 (D. Del. Jan. 6, 2015), a decision which, though not controlling, is relevant and persuasive. This

decision concerned a claim construction dispute between Merck and another generic company, Xellia, concerning the same patent, the same claim, the same claim phrase, and the same issue of whether the claim language requires that the acetate buffer be added separately. Id. at *4. Xellia had argued, as Fresenius does here, that the claim language requires that the acetate buffer be added separately. Id. The district court rejected Xellia's proposed construction, finding that it "reads a process limitation into a composition claim." Id. The district court held that the proposed construction, requiring the acetate buffer as a separate ingredient, imported manufacturing process elements into a claim that lacked any process requirements. Id. This Court agrees.

This Court rejects the interpretation proposed by Fresenius and agrees with that proposed by Merck. Fresenius has shown nothing close to a clear disavowal of particular manufacturing processes in the specification or prosecution history, and Merck is entitled to the full scope of its claim language. The claim language at issue requires only that an acetate buffer be present in the pharmaceutical composition, which is the construction Merck proposes. The Court, while agreeing with Merck, finds the exact wording of Merck's proposed construction somewhat awkward, as it suggests that the Court has affirmatively elucidated a question of meaning. To the contrary, the Court here rejects Defendant's proposed construction, and prefers to conclude that the disputed claim term has its plain and ordinary meaning – which requires only the presence of an acetate buffer in the composition.

For these reasons,

IT IS on this 30th day of October, 2015 hereby

ORDERED that, in U.S. Patent No. 5,952,300, subsection (c) of Claim 1 has its plain and ordinary meaning.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.